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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,544	03/19/2002	Laurent Di Costanzo	C1190/20009	7903

3000 7590 06/16/2005

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
11TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,544	COSTANZO ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
A 91618

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, and request for continued examination, all received on 27 May 2005.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 21-39 under 35 U.S.C. 103(a) over Liu *et al.* in view of Schmitz *et al.* and Valentine is hereby withdrawn.

Claims 21-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* (U.S. Patent No. 6,391,337) in view of Schmitz *et al.* (U.S. Patent No. 6,079,968) and Valentine (U.S. Patent No. 4,684,534).

The Hunter *et al.* patent teaches pharmaceutical dosage forms for a rapidly disintegrating tablet (See Column 5, Lines 27-45; Example 8; and Figure 3). Processes for making this tablet are disclosed (See Column 2, Line 52 to Column 3, Line 55). The tablets can variously comprise saccharides as inert fillers, including sucrose, dextrose, lactose, xylitol, fructose, and sorbitol (See Column 12, Lines 1-13). A lubricant, such as magnesium stearate, can be included in the tablets in amounts ranging from 0.01% to 4.0% by weight of the dosage form (See Column 10, Lines 1-23). A disintegrant may be included as well, such as sodium starch glycolate and cross-

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linked polyvinyl pyrrolidones (See Column 11, Lines 52-67). Other additives may also be included as well, such as flavorants, sweeteners, and coloring agents (See Column 15, Lines 41-53). The dosage forms are prepared by direct compression of a dry granulate (See Claim 1).

The Hunter *et al.* patent does not explicitly teach methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet.

The Schmitz *et al.* patent discloses a device that sprays powdered lubricants onto punches and dies of a tablet press. Such a device can be readily retrofitted into existing machinery and provide an improved method of tablet manufacture (See Column 1, Line 35 to Column 3, Line 36).

The Valentine patent is relied upon here as a teaching reference, stating that lubricants, having a particle size of 44 microns or less are known and desired within the art of manufacturing tablets. Furthermore, these lubricants may be further screened for smaller particle sizes (See Column 5, Line 54 to Column 6, Line 3).

It would be obvious to one of ordinary skill in the art to combine the teachings of the Hunter *et al.* and Schmitz *et al.* into the objects of the instantly claimed invention. One of ordinary skill in the art would be motivated to combine the Hunter *et al.* and Schmitz *et al.* references to create an improved process of making pharmaceutical dosage forms that meters out tablet lubricants in a more efficient manner in such a way that minimizes caking of lubricants onto tablet dies. As is been disclosed that the device disclosed in Schmitz *et al.* can be readily retrofitted into existing machinery, it is the position of the examiner that the two references can be combined by one of ordinary skill in the art with a reasonable expectation of success. As

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stated above, the Valentine reference is relied upon as a teaching reference solely with respect to what is known about the particles sizes of lubricants within the art.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments with respect to Claims 21-39 have been considered but are moot in view of the new grounds of rejection.

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Correspondence

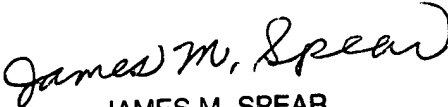
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0


JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615